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Evidence and recommendations on the use of telemedicine for the management of arterial hypertension: an international expert position paper

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ABSTRACT

Telemedicine allows the remote exchange of medical data between patients and healthcare professionals. It is used to increase patients' access to care and provide effective healthcare services at a distance. During the recent COVID-19 pandemic, telemedicine has thrived and emerged worldwide as an indispensable resource to improve the management of isolated patients due to "*lockdown*" or "*shielding*", including those with hypertension. The best proposed healthcare model for telemedicine in hypertension management should include remote monitoring and transmission of vital signs (notably blood pressure) and medication adherence plus education on lifestyle and risk factors, with video consultation as an option. The use of mixed automated feedback services with supervision of a multidisciplinary clinical team (physician, nurse or pharmacist) is the ideal approach. The indications include screening for suspected hypertension, management of older adults, medically underserved people, high-risk hypertensive patients, patients with multiple diseases, and those isolated due to pandemics or national emergencies.

Keywords: telemedicine; telehealth; e-health; m-health; arterial hypertension; COVID-19

BACKGROUND

Telemedicine (or telehealth) represents a revolutionary patient management approach combining various forms of information communication technology (ICT) in order to remotely deliver care, consultation, medical education, specific healthcare and clinical services, and for monitoring patients' parameters at distance [1]. It is a promising tool for improving access to care, empowering patients, influencing their attitudes and behaviors, and ultimately enhancing their medical conditions.

Telemedicine is expected to be increasingly utilized in the near future for acute and chronic disease management due to the ageing population with increased life expectancy and better survival from cardiovascular (CV) events leading to greater population health burden. The role of telemedicine has become increasingly clear in light of the COVID-19 pandemic. Bringing hypertensive patients into clinics for routine BP checks during a pandemic represents a serious risk, especially for older adults or those with underlying medical conditions. Social distancing and reduced mobility required to control the COVID-19 pandemic have highlighted and intensified the pressing need for telemedicine as the only way to manage a number of chronic conditions, including hypertension [2,3]. Furthermore, particularly in rural areas, practical issues in traveling to healthcare facilities make telemedicine attractive. COVID-19, combined with ongoing shortages of physicians and nurses, may affect access to appropriate care for an aging population with multiple morbidities and impaired mobility.

Hypertension is a good target for telemedicine, and in particular, for telemonitoring, as it is the most common and important risk factor for CV disease worldwide [4]. However, while telemedicine has been shown to improve blood pressure (BP) control as compared to standard care, its place in daily clinical practice is not yet clear [5]. Whilst most guidelines refer to it in the context of excluding white coat or masked hypertension, there are no current specific recommendations on the place of telemedicine in general hypertension management, with the partial exception of the 2017 American College of Cardiology (ACC) / American Heart Association (AHA) guidelines which suggest that telehealth strategies can be useful adjuncts to interventions shown to reduce BP for adults with hypertension [6].

SCOPE OF THE ~~CONSENSUS~~ POSITION PAPER

This ~~consensus~~ position paper aims to critically review the available evidence on the clinical usefulness and application and the current barriers and challenges for telemedicine in hypertension management. The different technological and clinical aspects will be presented and discussed. The

focus will be on telemonitoring, the telemedicine solution proven to be the most effective for hypertension management [7]. The potential of telemedicine for maintaining continuity of care for hypertensive patients in the time of infectious disease outbreaks, such as COVID-19, or more in general in national emergencies or disasters, will also be discussed. The role of telemedicine in the context of team-based hypertensive patient management programs will also be addressed, with indications for further progress in the field.

The document has been conceived and developed by a pool of international experts in the field and contains practical recommendations for the use of telemedicine tools in hypertension management.

The main concepts and recommendations are summarized in accompanying tables.

DEFINITIONS AND CLASSIFICATION

In this section, the current definition of telemedicine and related terms in the context of e-health is provided.

E-health embraces a wide range of multi-directional activities that make use of ICT to store, retrieve, share, exchange, and automate responses to health-related information for prevention, diagnosis, and treatment, and for monitoring, educational, and administrative purposes [8].

Telemedicine (or telehealth) allows the automatic exchange of medical information (e.g., health parameters, biological signals, diagnostic images, etc.), between individuals and their healthcare providers, in order to provide disease management at a distance [1,9]. A specific application of telemedicine is telemonitoring, which comprises remote monitoring of various vital and non-vital parameters and management of people usually with long term conditions. Telemedicine is often undertaken using mobile phones, known as m-health. A set of common definitions and examples for e-health and the different telemedicine services is provided in **TABLE S1** (please see <http://hyper.ahajournals.org>).

Currently, the most common way to deliver telemedicine services is by the Internet, often using mobile devices and using a “*closed-loop*” healthcare model also called “*Internet-of-Medical-Things*” (IoMT), which is schematically outlined in **FIGURE 1** and further discussed in the next sections of the paper [5].

SOLUTIONS

Telemedicine solutions involve several different tools aimed at the creation of a connected infrastructure of health systems and services, between the patient and the caregiver, or among

different healthcare professionals. Typical services provided through telemedicine are summarized in **TABLE S2**, many of which intersect to allow comprehensive patient management.

DEVICES

Telemedicine requires devices for collecting and exchanging information between remote sites. These devices can include a camera for video exchange, a microphone, and speakers for exchanging audio information and sensors for collecting specific vital or non-vital parameters. A list of potential devices is reported in **TABLE S3**.

COMMUNICATION AND TRANSMISSION

Usually, telemedicine services are provided using specific interfaces such as desktop or laptop computers, mobile phones (smartphones), PDAs, or virtual assistants (e.g., Amazon's Echo Dot or Google Home Mini) or tablet devices, that allow the collection and remote transmission of the information. Data gathering may occur through embedded tools or external sensors, such as cameras, microphones, or medical devices, and utilizing wired or wireless technologies (including Bluetooth, wifi, NFC, ZigBee, etc.). Telemedicine services commonly use websites or web portals to create interaction between users. However, a basic form of telemedicine is represented by telephone communication [10], with the caveat that management of hypertension and major chronic conditions in the absence of any physiological monitoring (i.e. based on symptomatology alone) is challenging. Text messaging (SMS) or e-mails represent other simple and popular ways of communication, while smartphone apps are becoming the norm.

Commonly, the interaction between patients and caregivers may be immediate (synchronous) or periodic (asynchronous). Typical examples of the first type of interaction are those occurring during live audio-video conferencing between a healthcare professional and the patient or during real-time transmission of vital signs from the patient's home to an emergency care unit. Examples of asynchronous interactions are represented by remote interpretation or telereporting of previously transmitted data, e-mail messaging or SMS, smartphone apps, or online programs for education. This asynchronous approach can be particularly helpful in managing large numbers of patients as messaging confirming normality, where appropriate, can be done quickly on a large scale leaving direct synchronous communication largely where parameters are not normal, and management needs to be adjusted.

Some practical examples of telemonitoring tools for hypertension management are summarized in **TABLE S4**.

SETTINGS AND POPULATIONS

SETTINGS

Current settings where telemedicine services for hypertensive patients are deployed, and their characteristics are summarized in **TABLE 1**. The different settings are interconnected according to a modern patient-centered model aiming at providing personalized or precision medicine. In this regard, telemedicine can foster a multidisciplinary and team-based approach to hypertension management provided that the different services are not siloed either technologically or professionally.

TARGET POPULATIONS

Telemedicine services may be targeted to two main types of populations.

Individuals who require screening for possible high blood pressure

The first and larger population includes all those individuals requiring screening for possible hypertension due to a potential risk based on genetic, environmental, or behavioral factors. This group would benefit from telemedicine in a general sense, including BP monitoring, along with screening for other risk factors (e.g., hypercholesterolemia, aortic aneurysm, bowel cancer screening, etc.).

Treated patients

The second group of patients includes those taking antihypertensive drug treatment, needing surveillance and follow-up. Two categories of patients may be identified. One includes patients at high risk of CV complications, suffering from comorbidities, resistant to antihypertensive treatment, or showing low adherence to the therapeutic plan. This category of patients needs more intensive telemonitoring and tighter surveillance. The second category of patients includes those at lower risk or less severe, with controlled BP, who may experience BP rises over time or more acute periods of uncontrolled BP and may thus benefit from intermittent telemonitoring.

IMPLEMENTATION OF TELEMEDICINE SERVICES WORLDWIDE

Exact estimates of the implementation of telemedicine services among hypertensive patients worldwide are lacking. However, recent statistics suggest that around the world seven million patients are managed by telemedicine, with the most popular applications targeting patients with

heart failure, hypertension and diabetes [5]. Europe and North America dominate the market of telemedicine, but emergent markets include Asia and Oceania. Although televisit and teleconsultation are the most popular telemedicine solutions, home-based telemonitoring relying on m-health apps is the fastest growing application of telemedicine and it is expected to help ongoing implementation of telemedicine, particularly in the context of a global pandemic [5].

SCIENTIFIC EVIDENCE FROM STUDIES

FEASIBILITY AND ACCEPTABILITY OF TELEMONITORING

In general, telemedicine in hypertension is feasible on a wide scale and well-received with excellent acceptability. In 13 studies (5 carried out in hospitals, 5 in general practices, 3 in the community) including 1,662 patients, the average adherence to telemedicine-based hypertension management programs was reasonably high: 76.8% of patients complied with the telemonitoring schedule (range 48-90%) [11]. In 10 studies (3 carried out in hospitals, 5 in general practices, and 2 in the community) enrolling 1,120 patients, 87.1% of the participants regarded the telemedicine solution as useful to manage their condition (range 69% - 100%) [11].

The recent coronavirus outbreak (COVID-19 pandemic) has shown what happens where patients are unable to visit their physicians at healthcare facilities due to fear of infection. Similar issues are relevant for people who find attendance at their healthcare provider difficult due to distance, disability, lack of transportation, or other commitments. In all of these situations, a telemedicine solution provides option for adequate care, and in most cases of hypertension, care requires telemonitoring of BP.

OVERALL PROOF OF EFFICACY

In this section, we present an umbrella review of the available systematic reviews and meta-analyses based on randomized controlled studies making use of telemedicine for the management of hypertension [12-26]. Given the evolution of ICT in recent years and the improvement in healthcare models based on telemedicine, we have focused on reviews published in the last decade, which reflect the current solutions available to healthcare professionals and patients.

The most successful telemedicine approach appears to be the one based on telemonitoring of BP and tracking of additional vital and non-vital signs with data exchange between patients and a case manager (usually a nurse or a pharmacist under the supervision of a clinician) through the web, e-mails, text messaging, or video consultation, integrated with education on lifestyle, risk factors and proper use of antihypertensive medications. The greatest effect observed is when delivery of the

intervention is proactive and not passive and when the intervention is driven by healthcare professionals - rather than patient-driven. Following the diffusion of mobile-apps, more direct involvement of the patient through self-management, perhaps under the supervision of a multidisciplinary clinical team (usually including one or more healthcare professionals supported by a trained non-healthcare professional with technical skills) seems to be promising. More patient involvement would allow increasing numbers of patients to be served by a single medical facility.

TABLE 2, summarizes the quality level, the methodology and the main results of systematic reviews and meta-analyses suggesting that randomized controlled studies published to date have shown greater BP reductions and a larger proportion of patients achieving BP control when a telemedicine approach is utilized compared to usual care. Some trials have compared BP telemonitoring with BP self-monitoring alone, suggesting that the telemedicine approach has an additional benefit in terms of BP control beyond self BP measurement.

As already discussed, the sustainability and long-term clinical effectiveness of these interventions remain unclear, with few studies looking at longer-term benefits beyond 12 months. Some evidence suggests ongoing effects even when interventions are stopped, but the optimal schedules for long term care once control is achieved are not established [27,28]. Understanding the ideal schedules and doses of the intervention (e.g. BP monitoring every month, or 3 months or 6 months) for long term care aspect is important to elucidate because arterial hypertension is a chronic and life-enduring condition.

The studies performed so far, however, were based on heterogeneous interventions, technologies, and study designs, which makes it difficult to identify the right solution for a given patient. The only strong evidence available from many studies is that solutions that are based on complex interventions, including not only telemonitoring but also multidisciplinary case management, education, and feedback to the patient, are the most effective [5]. Future studies should be more focused on this multifaceted multimodal approach and test such solutions in specific groups of hypertensive patients, such as those with resistant hypertension, those at high risk of developing CV diseases, or those with multiple comorbidities. In these patients, the cost-effectiveness of telemedicine may be higher, and the proof of effectiveness might favor the development of reimbursement models.

In some of the studies included in the meta-analyses, additional effects of the telemedicine intervention were observed and are summarized in **TABLE 3**. However, the strength of these effects is less consistent than BP reduction.

EFFECTIVENESS IN SPECIFIC HYPERTENSION SUBGROUPS

There are currently few studies and meta-analyses that have focused on evaluating the benefit of telehealth interventions compared to usual care in specific subgroups of hypertensive patients.

This evidence is discussed in the following paragraphs, and general recommendations is provided in **TABLE 4**.

Diabetes

Although several studies have tested the effectiveness of telemedicine in diabetic patients, with conflicting results [29], few studies have evaluated its impact in the presence of hypertension plus diabetes. In four randomized controlled studies performed among 734 hypertensive patients with comorbid diabetes, the intervention group based on telemonitoring plus nurse or clinician management resulted in greater reductions in BP, HbA1c, LDL-cholesterol, and a greater proportion of participants achieving their BP goal after 6 to 12 months compared to usual care [30-34]. Medication adherence was increased in one study and unchanged in another. In one study, patients achieving a SBP of <120 mmHg had lower average blood sugars than those with higher values. Thus, in patients with diabetes and hypertension, telemedicine has the potential for delivering intensified care to improve BP control.

Ethnicity subgroups

The effectiveness of telemedicine has also been verified in specific high-risk ethnic subgroups. The majority of the studies focused on Black Americans living in medically underserved areas. Four well-conducted randomized prospective controlled studies evaluated the impact of a 3 to 12 months nurse-managed telemedicine intervention among 1,533 African-Americans [35-37]. As compared to usual care, the intervention was associated with larger BP reductions and enhanced BP control, particularly in participants with higher hypertension stages. In another randomized controlled trial including 110 African-Americans with uncontrolled hypertension and lasting only one month, the authors found no difference in medication adherence and BP control between the usual care group and the intervention group receiving fully automated text messaging support [38]. Although the evidence of improved hypertension management with telemedicine is largely limited to African-Americans [39], there is one small randomized controlled study performed in 80 Koreans with concomitant obesity and hypertension which showed improved BP, body weight, waist circumference, and HDL-cholesterol after two weeks of a web-based intervention through a cellular phone and Internet SMS [40]. Another study without a control group included 359 Korean

Americans and showed improved BP levels after 12 months of a behavioral education intervention based on BP telemonitoring and bilingual nurse telephone counseling [41].

Low- and middle-income settings

In low- and middle-income countries, rapid globalization is progressively increasing the incidence of non-communicable diseases, and in particular of hypertension [42]. Given the lack of infrastructure and the need for patients to travel long distances from home to hospitals, telemedicine may be particularly beneficial in these settings. However, the current evidence of the effectiveness of telemedicine on non-communicable diseases in low- and middle-income countries is poor and mainly based on m-health interventions [43,44]. These studies show potential benefit from promoting physical activity and healthy diets, whereas results for other outcomes are conflicting and not definitive. Only one study including hypertensive patients specifically from clinics in Honduras and Mexico showed a benefit on BP control after six weeks of follow-up in 200 participants [45].

Pregnancy

A potential application of telemedicine is hypertension monitoring in pregnancy [46]. Although several studies show that m-health solutions may represent an important support for managing hypertensive disorders during pregnancy and improve current clinical practice, most of the evidence is limited to evaluating the feasibility of recruitment to a potential trial, usability of the proposed systems and improvement of maternal satisfaction [47,48]. Currently, no study has been of sufficiently large size to demonstrate an improvement in BP control or hypertension management in pregnancy, but two large studies are due to report in early 2021 [49].

Patients with cardiovascular or renal disease

The various telemedicine-based studies performed so far in hypertensive patients were, in some cases, conducted in patients who were also affected by additional CV disease or chronic kidney disease (CKD.) However, these studies did not provide any significant evidence to support the superiority of telemedicine for BP management in these patients. A recently published meta-analysis [50] investigated whether the effectiveness of self-monitoring of BP combined with a co-intervention, including telemonitoring, varied by co-morbidity. Self-monitoring of BP combined with intense co-interventions was more effective than low-intensity self-monitoring in patients with obesity and possibly stroke, but not in patients with coronary artery disease, diabetes, or CKD.

A meta-analysis including three studies with 680 participants with hypertension and stage III CKD showed a reduction in SBP in the telemedicine group after 1 to 2 years of follow-up; however, such reduction was not different from that observed in the usual care group [26].

EFFECTIVENESS IN SPECIFIC SETTINGS

Although most studies focusing on the efficacy of telemedicine among hypertensive patients have been performed in hospitals or outpatient clinics, some of them evaluated the impact of services deployed with the support of primary care physicians or pharmacists. These settings are particularly interesting because they represent the main approach to hypertension management in the community. Thus, they may represent the ideal ground for the dissemination of telemedicine in the context of hypertension management.

Community

As previously summarized in **TABLE 2**, many studies based on BP telemonitoring have been performed in a community setting. These studies show some evidence of effectiveness, particularly in the case of underserved areas and ethnic minorities. Furthermore, there is currently great interest in new hybrid solutions for remote management of hypertensive patients, based on devices (so-called “*connected kiosks*”) placed in community centers, waiting rooms of outpatients or primary care clinics, pharmacy or grocery stores [7]. These devices provide unsupervised measurement of BP and other relevant parameters, together with collection of information on the individual’s CV risk, lifestyle and physical fitness status. These unmanned solutions provide immediate automated feedback to the user with the option of requesting support from a remotely connected healthcare professional. At present, only results from feasibility studies are available for these tools, while their efficacy has still to be proven [51-54].

Primary care

One of the major studies evaluating the impact of telemedicine in hypertension management is the TASMINH2 Study. This study included 480 hypertensive patients recruited in 24 general practices in the UK. It evaluated whether an intervention consisting of self-monitoring of BP and self-titration of antihypertensive drugs, combined with telemonitoring of home BP measurements, could lead to substantial reductions of BP over one year of follow-up. This intervention was more effective in lowering BP than usual care [55] and also represented a cost-effective use of health care resources [56]. In another study, the TASMINH4, the same group assessed the efficacy of self-monitored BP, with or without telemonitoring, vs. usual care for antihypertensive titration in 142

general practices and 1,182 high-risk hypertensive patients with poorly controlled BP [57]. After 12 months of follow-up, self-monitoring of BP, with or without telemonitoring, was associated with lower BP values and lower costs than usual care [58]. Although this study did not find any significant difference in the effect of telemonitoring compared to that of self-monitoring after 12 months, BP in the telemonitoring group dropped more quickly (at six months) than in the self-monitoring alone group, an effect which is desirable in high-risk patients to further decrease the risk of CV events. Furthermore, telemonitoring was cost-effective, even when compared to self-monitoring alone in linked modeling work [58].

Another major randomized controlled trial is the HITS Study, conducted in 20 primary care practices in south east Scotland and involving 401 hypertensive patients with uncontrolled day-time BP. In this study, the intervention consisted of self BP measurement with transmission of BP readings to a secure website for review by the attending physician or nurse, with optional automated feedback to the patient by text or e-mail. After six months day-time BP was reduced significantly more in the intervention than in the usual care group, but was more expensive [59,60].

In Italy, the TELEBPCARE Study assessed whether a home BP telemonitoring intervention with case management by the general practitioner could improve BP control [61]. The study involved 12 general practices and 391 hypertensive patients. After six months of follow-up, ambulatory BP control was improved in the intervention group, with less frequent treatment changes, a better quality of life, and lower management costs.

Finally, in a Canadian study recruiting 223 primary care hypertensive patients of 8 different practices, after one year of follow-up, ambulatory BP was lower, and more patients achieved the BP target in the nurse-led BP telemonitoring group under physician supervision [62]. The intervention was also associated with more-physician-driven antihypertensive dose adjustments or changes in medications and a trend toward improvement in medication adherence.

A summary of the effect of the intervention vs. usual care on office and ambulatory BP in the five studies is presented in **FIGURE S1** [55,57,59,61,62].

Pharmacy setting

Few randomized controlled studies have evaluated the impact of community pharmacists in the management of hypertensive patients through telemedicine (so-called “*telepharmacy*”) [24]. In these studies, a physician-pharmacist collaborative intervention based on home BP telemonitoring together with patient education on lifestyle, drug therapy, and CV risk factors control was associated with an enhanced BP control as a consequence of antihypertensive medication intensification and optimization. As shown in **FIGURE S2**, the magnitude of BP reductions and

proportions of patients at target following a 6 to 12-month pharmacist's intervention were significantly larger than those observed in patients randomized to usual care [28,63-71]. The benefit of the pharmacist's intervention was consistently reduced or even abolished months after its withdrawal, highlighting the importance of the sustainability of the intervention in the long-term. Interestingly, the few studies that also evaluated the cost-effectiveness of the intervention documented that the improved BP control could be achieved at a relatively low cost compared with the usual care approach. The management of uncomplicated mild hypertensive patients by pharmacists licensed to prescribe or adjust medications, as occurs now in many states in the US, may help free up physicians to manage more complex patients and may be a more cost-effective way to practice.

More recently, the TEMPLAR project documented an improved screening of high BP by the introduction of 24-hour ABPM with medical telereporting and telecounseling in Italian community pharmacies [72].

BENEFITS

The major benefits of telemedicine services for hypertension management are summarized in **TABLE S5** and discussed below.

Telemedicine may help to build and maintain an enduring and long-term relationship between patients and their healthcare providers. Telemedicine may help empower hypertensive patients, influencing their attitudes and behaviors, and promote self-management, with improvement in the patient's medical condition. Digital interventions can help reinforce and individualize the physician-patient relationship, and thus improve BP and CV risk control [73]. Technological innovation due to telemedicine may bring better professional cooperation, information sharing, decision support, and flexibility to the healthcare system. Remote patient monitoring through telemedicine allows physicians and health facilities to expand their reach, beyond their own offices, and to easily provide services to an increased number of patients, with consistent savings in time demands, and with the same content quality of traditional in-person consultations. Where face-to-face contact is difficult due to fear of infection (e.g., in time of pandemic such as that due to COVID-19) or due to isolation (as in the case of natural disasters), disability or geography, then telemedicine provides opportunities for care where none would otherwise be possible [2]. In particular, telemedicine enhances the monitoring, tracking, and communication of various biometric information, enabling greater engagement and partnership of patients in their care, reducing their stress. In the case of hypertensive patients, telemedicine services can be used to easily and rapidly communicate to the referring doctor the occurrence of acute symptoms or sudden BP rises. Finally,

telemedicine services offer hypertensive patients the access to diagnostic procedures that might not be available otherwise, without the need to cover long distances (e.g., ambulatory BP monitoring or electrocardiogram facilities in community pharmacies linked to telemedical reporting services).

BARRIERS AND CHALLENGES

The incomplete evidence on the clinical efficacy and economic benefit of telemedicine provided so far by randomized studies, technological barriers, high costs of devices, heterogeneity of solutions and technologies, lack of infrastructures and standards, lack of reimbursement, privacy and security issues, have all hindered the dissemination of telehealth strategies and their adoption in the daily practice of healthcare professionals and patients [5,74] (**TABLE S6**).

Currently, several services are available on the market, and none appears to be a benchmark solution to be used as a reference to standardize a healthcare model based on telemedicine. Existing systems are not interoperable and are rarely integrated into the existing healthcare systems and/or electronic health records.

The development of telehealth programs requires investment in infrastructure, including the purchase and maintenance of computer hardware and related software, as well as secure means for data transmission, compliant with current privacy regulations. Additional costs are those for recruitment and licensing of appropriate professionals for service management and those of providing training and support services to staff and users. The costs related to implementation of telemedicine services, together with the lack of reimbursement of services and consultations, play a critical role in preventing or delaying the development and diffusion of telemedicine solutions.

Poor informatics skill levels, lack of motivation, and inadequate knowledge of the clinical usefulness of telemedicine represent major cultural barriers to the routine use of telemedicine, from both doctor's and patient's perspectives. The educational level and features of the patients targeted for the intervention are also important. Resistance to adopting new models of care affects both patients and healthcare workforces. To facilitate the diffusion of telehealth services, efforts should be dedicated to their integration into the existing organizational structures and to provide institutional support to deliver these services.

REGULATORY AND LEGAL ISSUES

Several regulatory and legal issues need to be addressed to ensure the quality of telemedicine services in hypertension management. These aspects are briefly summarized in **TABLE S7** and extensively discussed in the next paragraphs.

Telemedicine services are based on hardware and/or software and provide medical diagnosis and care: thus, they must be classified as medical devices. This means that telemedicine equipment must be developed, validated and certified according to the recommendations and indications of regulatory bodies. This is particularly relevant for health apps: they are growing rapidly on the market, but the majority of them lack an appropriate test for efficacy and quality and are often labeled as wellness or fitness products to circumvent regulation when, indeed, most of them act as medical devices [75]. These considerations strongly emphasize the importance of scientific validation for health apps content, and the need of demonstrating their usefulness through properly designed clinical studies [76-78].

At the end of the process of development of a telemedicine solution and before the product is placed on the market and used by healthcare providers and patients, the manufacturer must provide evidence of clinical validation and submit the product to the authority for certification as a medical device. In Europe, according to the new EU Regulation 2017/745, software to be used for medical purposes (*“diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease”*), is defined as a medical device. As such, it must be validated according to state of the art, taking into account the principles of the development life cycle, risk management, validation and verification, and post-marketing surveillance [79].

In the USA, the FDA regulation states that telemedicine software (or m-apps) meet the regulatory definition of the device if *“intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and is not dependent upon being metabolized for the achievement of any of its primary intended purposes”* [80].

A further aspect of telemedicine that is often underestimated is the need for clear guidelines about its application and the need for training, certification, and licensing of operators. This applies to doctors, nurses and pharmacists, important groups often handling telemedicine solutions. Indeed, healthcare professionals used to work in a traditional face-to-face care setting, may need adequate training in order to be effective when providing services with telemedicine. In the USA, the American Telemedicine Association offers a telemedicine accreditation program for online, synchronous patients consultations, which promotes patient safety, transparency of operations, and adherence to all relevant laws and regulations [81]. There are also accreditation programs designed for organizations that provide telemedicine services, such as those promoted by the Review Accreditation Commission [82]. Since telemedicine crosses the boundaries of individual countries,

while physician licenses do not, a major challenge to be faced in the future is whether special regulations are needed for doctors to provide telemedicine services (e.g., telemonitoring, televisit or teleconsultation) to patients dwelling in another country. In the USA, for instance, 12 states foresee a special license allowing the physician to practice across state lines for telemedicine only, while six states require the physician to register if he wishes to practice across state lines [83]. In Europe, doctors can freely practice across the EU member states. However, language is a major challenge to provide telemedicine services to local patients.

Privacy and security issues are important when data are traveling through the web, and they are particularly important due to the increasing use of cloud solutions. In particular, the large availability of user-friendly smartphones and m-apps is raising great concerns among doctors and patients about lack of transparency regarding the utilization and transfer of data, and how data are protected from potential breaches and misuse.

Since telemedicine involves the collection and sharing of patients' health information, safeguards are needed to be put in place to secure the privacy and safety of these data, to minimize the risk of a data breach. Any data transmission through the web must be encrypted to ensure security. Servers where data are stored must be protected from intruders with firewalls, antivirus software, and anti-ransomware tools. Regular data backups and fast procedures for data restoration, or even data mirroring must be ensured.

Compliance with privacy regulations by telemedicine developers and providers is mandatory to guarantee the integrity of users' health data. In Europe, the General Data Protection Regulation (GDPR) 2016/679 harmonizes data privacy law across Europe to protect and empower all European citizens' data privacy extending the concept of personal data and liability to all data processors [84]. In the USA, the Health Insurance Portability and Accountability Act (HIPAA) ensures similar security standards for any medical activity associated with telemedicine [85].

TELEMEDICINE IN THE SPOTLIGHT AT THE TIME OF COVID-19 AND NATURAL DISASTERS

During the public health emergency due to COVID-19 telemedicine has thrived and emerged worldwide as an indispensable resource to improve surveillance of patients, contain the spread of the disease, favor early identification and prompt management of infected people, but particularly to ensure continuity of care of vulnerable patients with multiple chronic diseases, including hypertension [2,3]. The recent pandemic has strongly promoted the use of remote monitoring and televisits, where in-person consulting has been greatly reduced or impossible [86,87].

In the next paragraphs, we present the experience collected in the countries of the experts involved in the development of the position paper during the COVID-19 pandemic and during similar national emergencies.

In the UK, during the COVID-19 pandemic, there has been a marked swing towards BP telemonitoring in antenatal care, underpinned by rapidly-produced national guidelines, with around 80% of maternity units adopting a program of BP self-monitoring for pregnant women [88]. In Scotland, an integrated telemonitoring system for hypertension implemented in the last few years at scale in 75 primary care practices and used by 3200 patients with established hypertension, has seen a marked increase in the demand and provision of the services by hypertensive patients locked down due to the infectious outbreak [89].

In Italy, the national health system struggled to sustain the wave of COVID-19 patients due to a shortage of personnel, devices and intensive care unit beds. During the two months of lockdown, patients with chronic disease and hypertension, kept at distance by hospitals, general practices and outpatient specialist clinics, markedly increased their access to health content on the Internet seeking qualified and certified telehealth services able to help manage their condition. A significant increment in the use of home telemonitoring solutions based on m-health has been observed during the lockdown due to the halting of face-to-face visits (+768% new active users and +840% new data exchanged). On the other hand, in the same period, telemedicine and telecounseling services daily provided to patients through community pharmacies and general practices showed a dramatic drop (-881%), because of the reduced access of patients to these premises for fear of contagion [90]. Unfortunately, the use of telemedicine by patients at home was hampered by a limited ICT infrastructure.

In the US, because of COVID-19, governmental policies have been introduced to enable broad expansion and rapid implementation of telemedicine [2]. There was a relaxing of federal regulatory use of telemedicine including allowing the use of telemedicine across state lines and increased reimbursement by Medicare (and many other insurers) for telehealth visits for the first time due to COVID-19, with close to in-person rates. The government had also funded telehealth services, particularly in underserved clinics [91]. Besides, there was continuing work to adapt programs to support individuals during the pandemic [92].

In Canada, the pandemic has pushed physicians to adopt make-shift solutions to provide care [93]. Televisits are now commonplace with the telephone being the primary communication tool. However, physicians have soon realized that televisits with no monitoring information, no updated lab results and no physical assessment have limited value. Most are dissatisfied with the experience.

At this point it is unclear how the patients viewed the experience and whether telemedicine will boost after the pandemic.

Telemedicine and BP telemonitoring have also proved to be effective approaches in natural disaster situations. In Japan, at the time of the Great East Japan Earthquake in 2011, the Disaster Cardiovascular Prevention system providing cloud-based BP telemonitoring, has been introduced into the disaster area to manage patients with “*disaster hypertension*” [94,95] In the acute phase, this telemonitoring system was effective to pick up the “*real-time*” high-risk patients based on daily trends of self-measured BP. Among the patients followed through the system, the doctors actually identified treated patients with excessive BP reduction by dehydration, or with sudden and significant increment in BP, and could contact them in order to adjust therapy [96]. The telemonitoring system reduced the frequency of patients’ visits during the immediate time following the disaster, but did not miss the high-risk patients confined at home. In a stable situation after the acute phase, this system was effective for proactive BP control [97].

FINAL RECOMMENDATIONS

Many current hypertension guidelines do not contain specific recommendations on the use of telemedicine for hypertension management [98-104]. As summarized in **TABLE S8**, only American guidelines clearly recommend the use of telemedicine to confirm the diagnosis of hypertension and as an adjunct on top of the standard intervention to improve BP control and adherence [6].

Undoubtedly, evidence about the usefulness of telemedicine for the management of hypertensive patients is far from being definitive or consistent. However, in the last decade, the number of well-conducted and large studies performed in different subgroups of hypertensives and different settings has increased. Additionally, the technology has much improved, allowing a more widespread diffusion of telemedicine solutions among healthcare doctors and patients. In this sense, the proliferation of m-apps has raised awareness among the general public about the importance of telemedicine. However, it has also drawn attention to the danger of uncontrolled connected health.

TABLE 5 summarizes proposals for possible telemedicine provision models based on the evidence provided and discussed in the previous sections and originating from the consensus of the international experts involved in the present publication.

In conclusion, telemedicine represents a useful approach to help deliver effective care to hypertensive patients and optimize their management by doctors and other care managers. The current evidence supports its use in patients with difficult to treat hypertension or poorly adherent to medication management. However, more scientific evidence is needed to demonstrate the

effectiveness of telemedicine in other specific subgroups and beyond effective BP-lowering and control. Besides this aspect, we must acknowledge that several barriers still limit the implementation of telemedicine in the routine clinical management of the hypertensive patient, including the fact that telemedicine is considered as an add-on to existing care rather than an indispensable tool to be blended in current care delivery. This pool of experts is confident that in the future, telemedicine will be more and more embedded in standard delivery care models of hypertension with great benefits for patients and their doctors. Eventually, the current COVID-19 crisis will boost this process.

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AUTHORSHIP

All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval to the version to be published. Stefano Omboni made the literature search, drew the pictures and tables, and drafted the manuscript. Richard McManus contributed to its refinement. All authors critically revised and approved the final manuscript.

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NOVELTY AND SIGNIFICANCE

What is new?

- This paper summarizes the evidence for the use of telemedicine for hypertension and provides recommendations for its implementation internationally, issues not covered in many current hypertension guidelines.

What is relevant?

- Large randomized controlled studies in the last decade have shown that the use of telemedicine is associated with an improved blood pressure control compared to usual care
- Complex interventions including blood pressure telemonitoring, multidisciplinary case management, education and feedback to the patient are the most effective

Summary

- Telemedicine is recommended for the screening of suspected hypertension and the management of older adults, medically underserved people, high-risk hypertensive patients, and those isolated due to pandemics

LEGENDS

Figure 1. Diagram of basic telehealth services and their workflow. EHR: Electronic Health Record; NFC: Near Field Communication; PDA: Personal Digital Assistant; IoMT: Internet of Medical Things; Mic: Microphone [from 5 by permission].

Table 1. Service settings. AHP: Allied Health Professional.

<ul style="list-style-type: none">• General community setting<ul style="list-style-type: none">- Interactive kiosks located in waiting rooms, supermarkets, etc. (unattended)• Health-related community setting and primary care<ul style="list-style-type: none">- General practitioners and practice nurses- Community pharmacists- Homecare services• AHP services, interfaces between primary and secondary care services• Secondary care<ul style="list-style-type: none">- Outpatient clinics (specialists)- Hospital emergency departments, intensive care units, medical imaging services, maternity services• Tertiary care<ul style="list-style-type: none">- General Hospitals- Hypertension centers
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Table 2. Systematic reviews and meta-analyses of studies documenting the efficacy of telehealth compared to usual care in hypertension management. RCT: Randomized Controlled Studies; CKD: Chronic Kidney Disease; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure; BP: Blood Pressure; eGFR: estimated Glomerular Filtration Rate.

Author (year)	Type of intervention	Type of subjects	Setting	No. studies (comparisons)	No. subjects	Publication year (range)	Quality of the studies and/or publication bias	Median length (range) of follow-up (weeks)	Outcomes assessed	Summary of main results
Omboni et al. (2011) [12]	BP exchanged through landline or mobile telephone/modem transmission or Internet + patient education + case manager	Hypertensive patients (1 study in obese and 1 in people with diabetes only)	Mainly general practices or community clinics	12 RCTs	4,389	1996-2010	<ul style="list-style-type: none"> • 12 acceptable • Low publication bias 	24 (8-240)	<ul style="list-style-type: none"> • BP changes • Rate of BP control • Number of antihypertensive drugs 	<ul style="list-style-type: none"> • Office (but not ambulatory) BP was reduced significantly more in patients randomized to the intervention • Office BP control (percentage of patients at target) was better in the telemedicine group • The intervention was associated with a significantly increased use of antihypertension medications
Agarwal et al. (2011) [13]	BP telemonitoring	Hypertensive patients	Mainly community and general practice	7 RCTs	1,510	1996-2008	<ul style="list-style-type: none"> • No publication bias 	24 (8-48)	<ul style="list-style-type: none"> • BP changes 	<ul style="list-style-type: none"> • Greater SBP reduction was observed compared to usual care in subjects using telemonitoring than in those performing self-BP monitoring without remote transmission and counseling
Verberk et al. (2011) [14]	BP exchanged through landline or mobile telephone/modem transmission or Internet + patient education + case manager	Hypertensive patients	Mainly general practices or community clinics	9 RCTs	2,501	1996-2010	<ul style="list-style-type: none"> • Low publication bias 	26 (8-52)	<ul style="list-style-type: none"> • BP changes 	<ul style="list-style-type: none"> • Larger office BP reduction in the intervention group • The difference in the effect size of the intervention is larger if treatment is not modified

Author (year)	Type of intervention	Type of subjects	Setting	No. studies (comparisons)	No. subjects	Publication year (range)	Quality of the studies and/or publication bias	Median length (range) of follow-up (weeks)	Outcomes assessed	Summary of main results
Omboni et al. (2013) [15]	BP exchanged through landline or mobile telephone/modem transmission or the Internet, e-mail + patient education + case manager	Hypertensive patients (1 study only obese, 2 studies only diabetics)	Mainly general practices or community clinics	23 RCTs	7,037	1996-2011	<ul style="list-style-type: none"> • 23 acceptable • Low publication bias (except for cost analysis) 	24 (8-240)	<ul style="list-style-type: none"> • BP changes • Rate of BP control • Number of antihypertensive drugs • Adherence to treatment • Number of office visits • Healthcare costs • Quality of life • Adverse events 	<ul style="list-style-type: none"> • Significantly improved office BP changes and control with the intervention • Larger prescription of antihypertension medications in the intervention group • No difference in adherence to treatment and number of office consultations • Intervention is cost-effective if only medical costs are considered (excluding the costs for the technology) • Improved physical component of quality of life • No difference in the risk of adverse events
Zullig et al. (2013) [16]	Home BP monitoring and nurse telephone call + behavioral modification and medication management	Hypertensive patients (stroke or TIA)	Community or Hospital	7 RCTs	2,081	2009-2013	<ul style="list-style-type: none"> • Very poor (only descriptive review and few studies included) 	12 (6-24)	<ul style="list-style-type: none"> • BP changes • Rate of BP control • Adherence to treatment 	<ul style="list-style-type: none"> • Larger BP reduction in the intervention group in 2 studies, no effect in 3 studies • Improved BP control with the intervention (2 studies) • More medication changes in the intervention group (1 study) • No difference in medication adherence (1 study)
Liu et al. (2013) [17]	Internet-based lifestyle interventions and BP measurement during a face-to-face visit	Mainly hypertensive patients (plus obese, diabetics and post-menopausal women)	Mainly community and general practice	11 RCTs 2 not RCTs	2,221	2004-2012	<ul style="list-style-type: none"> • No publication bias for SBP • Low publication bias for DBP 	14 (8-48)	<ul style="list-style-type: none"> • BP changes 	<ul style="list-style-type: none"> • Internet-based lifestyle intervention significantly reduced BP • The greatest SBP reduction was observed for interventions that lasted at least 6 months, used 5 or more behavior change techniques or delivered health messages proactively

Author (year)	Type of intervention	Type of subjects	Setting	No. studies (comparisons)	No. subjects	Publication year (range)	Quality of the studies and/or publication bias	Median length (range) of follow-up (weeks)	Outcomes assessed	Summary of main results
Niznik et al. (2017) [18]	Pharmacist-led telephonic clinics, pharmacist management of BP through web-communication, electronic messaging (e-mail) or telemonitoring + education	Hypertensive patients (\pm CKD)	Pharmacies	7 RCTs	3,336	2008-2014	<ul style="list-style-type: none"> Not evaluated 	48 (24-72)	<ul style="list-style-type: none"> BP changes Rate of BP control Morbidity and mortality 	<ul style="list-style-type: none"> Significant decrease in BP with pharmacist intervention compared to usual care Larger proportion of patients with controlled BP in the intervention group No differences in deaths, hospitalizations, number of days spent in the hospital, Emergency Department visits or Skilled Nursing Facility admissions
Tucker et al. (2017) [19]	Web or phone feedback plus education, counseling or telecounseling	Hypertensive patients	Primary care, outpatients and community	18 RCTs	9,175	2007-2014	<ul style="list-style-type: none"> Low risk of bias 	48 (4-72)	<ul style="list-style-type: none"> BP changes Rate of BP control 	<ul style="list-style-type: none"> Self-monitoring of BP with counseling or tele counseling or with web/phone feedback plus education is associated with a significantly larger BP reduction and a higher proportion of patients at a target than usual care Results are consistent at both 6 and 12 months Trend to attenuation of the effect for patients followed up for longer than 1 year The effect is more consistent in people on fewer BP medication and with higher baseline BP

Author (year)	Type of intervention	Type of subjects	Setting	No. studies (comparisons)	No. subjects	Publication year (range)	Quality of the studies and/or publication bias	Median length (range) of follow-up (weeks)	Outcomes assessed	Summary of main results
Xiong et al. (2018) [20]	m-Health interventions (apps, SMS, voice calls or e-mails used as reminders and/or health education and/or lifestyle-related recommendations, digital medicines, wireless BP monitoring, and electronic medication tray)	Hypertensive patients		16 RCTs 1 non-RCT 4 before-and-after studies without a control group		2000-2017	<ul style="list-style-type: none"> • 6 good • 7 fair • 8 poor 	12 (4-48)	<ul style="list-style-type: none"> • Medication adherence 	<ul style="list-style-type: none"> • 12 out of the 21 studies found improvements in the patients' medication adherence
Choi et al. (2019) [21]	Data transmitted by telephone, the Internet, mobile phones or e-mail	Hypertensive patients	Urban	27 RCTs	9,435	1996-2017	<ul style="list-style-type: none"> • Low risk of bias 	24 (8-52)	<ul style="list-style-type: none"> • BP changes • Rate of BP control 	<ul style="list-style-type: none"> • Office (but not ambulatory) BP was reduced significantly more in patients randomized to the intervention • Office BP control (percentage of patients at target) was better in the telemedicine group • The intervention was more effective in smaller cities compared to larger cities • The intervention was similar regardless of the medically underserved areas

Author (year)	Type of intervention	Type of subjects	Setting	No. studies (comparisons)	No. subjects	Publication year (range)	Quality of the studies and/or publication bias	Median length (range) of follow-up (weeks)	Outcomes assessed	Summary of main results
Ma et al. (2019) [22]	e-Health interventions (interactive wireless communication by smartphone, computer, and personal digital assistance tools, self-care behavioral change or education dissemination)	Hypertensive patients	Mainly community and general practice	14 RCTs	3,998	2008-2017	<ul style="list-style-type: none"> • 14 good • Low risk of bias 	24 (12-96)	<ul style="list-style-type: none"> • Physical outcomes (BP, body weight, cholesterol) • Self-care behavioral outcomes (medication adherence, sodium intake, healthy diet, physical activity, smoking, alcohol consumption) • Psychosocial well-being (anxiety, stress, depression, quality of life) 	<ul style="list-style-type: none"> • The intervention significantly reduced office BP and significantly decreased the proportion of patients with inadequate BP control and their body weight • The sodium intake was reduced significantly more in patients randomized to the intervention • The effectiveness of the intervention on self-care behavioral change and psychosocial wellbeing is insufficient
Lu et al. (2019) [23]	m-Health interventions (mobile phones or wearable sensors) transmitting data to care providers	Hypertensive patients	Mainly community and general practice	11 RCTs	4,271	2007-2019	<ul style="list-style-type: none"> • 4 high • 7 low • Low publication bias 	48 (4-72)	<ul style="list-style-type: none"> • BP changes 	<ul style="list-style-type: none"> • The intervention was associated with a significantly larger BP reduction • No significant differences in BP reduction were observed between trials of shorter and longer duration • Trials with more frequent weekly BP measurement weekly had a larger effect on DBP than those with less frequent measurements • The magnitude of BP reduction was larger among subjects with inadequate baseline BP control than among those with adequate baseline BP control

Author (year)	Type of intervention	Type of subjects	Setting	No. studies (comparisons)	No. subjects	Publication year (range)	Quality of the studies and/or publication bias	Median length (range) of follow-up (weeks)	Outcomes assessed	Summary of main results
Omboni et al. (2019) [24]	BP exchanged through mobile phone, telephone, modem, Internet or e-mail + patient education + pharmacist management	Hypertensive patients	Community pharmacies	4 RCTs	1,565	2008-2018	<ul style="list-style-type: none"> • Not evaluated 	96 (24-216)	<ul style="list-style-type: none"> • BP changes • Rate of BP control • Cost-effectiveness 	<ul style="list-style-type: none"> • BP reductions and proportions of patients at target following a pharmacist' intervention were significantly larger than those in the usual care group • The benefit of the pharmacist's intervention was markedly reduced or abolished months after its withdrawal • Improved BP control was achieved at a relatively low cost compared with the usual care (3 studies)
Alessa et al. (2019) [25]	m-Health interventions (smartphone app, + e-mail, SMS, voice calls used as contact and/or health education and/or lifestyle-related recommendations, electronic medication device, wireless BP monitoring)	Patients with hypertension, metabolic syndrome, obstructive sleep apnea, and obesity	Primary care or community clinics, outpatient clinics, Hospitals	9 RCTs 5 non-randomized studies	2,402	2012-2017	<ul style="list-style-type: none"> • 2 good • 4 fair • 8 poor 	24 (8-52)	<ul style="list-style-type: none"> • BP changes 	<ul style="list-style-type: none"> • The majority (10 / 14) of studies demonstrated a positive effect on SBP, whereas the others showed a neutral effect • Apps that are incorporating more comprehensive functionalities are likely to be more effective
Luo et al. (2019) [26]	BP telemonitoring + telephone follow-up or interactive video consultation + education program	Patients with hypertension and CKD stage III	Community and outpatient clinics	3 RCTs	680	2011-2014	<ul style="list-style-type: none"> • 3 moderate quality • 3 low risk of bias 	24 (24-48)	<ul style="list-style-type: none"> • BP changes • Creatinine changes • eGFR changes 	<ul style="list-style-type: none"> • SBP was reduced by the intervention and DBP increased, with no statistically significant difference compared to usual care • BP control rates were not significantly improved • Serum creatinine was non-significantly decreased, and eGFR was maintained at baseline levels

Table 3. Summary of the evidence for benefits of telemedicine in hypertension management compared to usual care.

Type of outcome	Effect	Strength of evidence
• BP reduction	Increased	Moderate
• BP control	Improved	High
• Use of antihypertensive medications	Increased	Low
• Adherence to antihypertensive treatment	Improved	Very low
• Frequency of office consultations	Reduced	Low
• Quality of life or psychosocial wellbeing	Improved	Low
• Drug safety	Improved	Very low
• Costs	Reduced	Very low
• Deaths and/or hospitalization	Reduced	Very low

Table 4. Effectiveness of telemedicine on different subgroups of hypertensive patients. CKD: Chronic Kidney Disease.

Significant effects	Non-significant effects or insufficient evidence
<ul style="list-style-type: none"> • Patients with higher BP • Obese patients • Patients with previous stroke • Diabetic patients • African-Americans (living in medically underserved areas) 	<ul style="list-style-type: none"> • Patients with coronary artery disease • Patients with CKD • Patients in developing countries • Pregnant women

Table 5. Recommendations for hypertension management with telemedicine: proposed healthcare models. BP: Blood Pressure; COVID: COrona Vlrus Disease.

<ul style="list-style-type: none"> • Type of service <ul style="list-style-type: none"> - Remote monitoring of vital signs (e.g., BP) + medication adherence + education on lifestyle and risk factors + asynchronous feedback (best option) - Combined with telephone or video consultation (optional) • Type of case management and feedback <ul style="list-style-type: none"> - Automatic responses based on interpretative algorithms - Attended services (non-medical case manager, physician, nurse or pharmacist) - Mixed automatic services with multidisciplinary clinical team supervision (ideal option) • Type of medical intervention <ul style="list-style-type: none"> - Structured care - Integrated multilevel management by different healthcare professionals (nurse or pharmacist) (best option) • Target populations: <ul style="list-style-type: none"> - Screening for suspected hypertension (or white-coat hypertension) - Ongoing management of hypertension, especially: <ul style="list-style-type: none"> - Older adults - Medically underserved populations (deprived areas) - High-risk hypertensive patients (resistant hypertensives, patients with poor medication adherence) - Multimorbidity (diabetes, obesity, stroke) - Where face to face consultation is difficult due to geography or pandemic or other national emergencies and consequent lockdown (e.g., COVID-19)
